

Consultant year-end index

VOLUME 21, JANUARY-DECEMBER 1981

INDEX TO MAJOR SUBJECTS

- Abdominal mass, differentiation.** Katz AR. Dec 27.
- Abdominal pain.** See **Gastrointestinal disorders.**
- Acidosis.** See **Lactic acidosis.**
- Acoustic nerve tumors, what to do about.** Gacek RR. July 110.
- Adolescents, contraception for adolescent girls.** DeLia JE. March 63.
- fatigue.** Melnick A. July 150.
- iron deficiency and anemia.** Lanzkowsky P. Aug 164.
- limp, cause.** Gucker T 3rd. June 194.
- pitcher's elbow.** Grana WA. June 33.
- sexual abuse of, how to recognize and deal with a delicate problem.** Downes M, Orr DP. Nov 37.
- treating the emerging adult.** Daniel WA Jr. Sept 107.
- Adult respiratory distress syndrome.** See **Respiratory diseases.**
- Agoraphobia.** See **Clinical Cases** No. 80, April 262.
- Alcohol and medications, interactions.** Calesnick B. Aug 193.
- Alcoholism, and hard-drug dependency among physicians, a compassionate approach.** Cruse J. Nov 297.
- meeting head-on; the subtler side.** Whitfield CL. May 81; June 101.
- Allergic alveolitis.** See **Clinical Cases** No. 77, Jan 188.
- Allergies, allergic dermatitis, complications and management.** Vander Ploeg DE. Sept 65.
- allergic urticaria.** Prawer SE, Katz HI, Hien NT. Feb 265.
- poison ivy rash? maybe, maybe not.** Schorr WF. July 37.
- Aminoglycosides.** See **Drugs.**
- Anemia, aplastic, from 'gun oil,' benzene compound (Brief Consultation).** Schwartz SO. Aug 158.
- iron deficiency in adolescents.** Lanzkowsky P. Aug 164.
- See also Puzzling Cases** Woman with anemia.
- Angioedema, better treatment in sight.** Sheffer AL. Sept 173.
- Ankle ligament injuries, proper management requires meticulous appraisal.** Bonamo JJ. Oct 147.
- Antiarrhythmic drugs.** See **Drugs.**
- Antibiotics.** See **Drugs.**
- Antihypertensive drugs.** See **Drugs.**
- Anti-inflammatory drugs.** See **Drugs.**
- Antiparasitic drugs.** See **Drugs.**
- Anxiety.** See **Clinical Cases** No. 80, April 262.
- Aortic valve disease.** See **Heart.**
- APGAR questionnaire, helping treat 'whole' patients.** Milkstein G. March 170.
- Apnea, sleep, and narcolepsy, recognition and management.** Orr WC. Feb 202.
- Arm.** See **Burns and Puzzling Cases, Laborer with the sore arm.**
- Arrhythmias, of acute myocardial infarction, treating.** Biddle TL. March 38.
- postinfarction (Brief Consultation).** Kinlaw WB. May 205.
- tachyarrhythmias, refractory, marshalling old and new weapons.** Cohen SI. Oct 107.
- Arteritis, occult giant cell.** Healey LA Jr. July 227.
- Arthritis, nonsteroidal anti-inflammatory drugs, which to use?** Pope RM. Feb 29.
- psoriatic, diagnostic dilemmas and therapeutic options.** Namey TC. Oct 236.
- rheumatic syndromes, diagnosing short-lived, self-limited.** Healey LA. Aug 97.
- rheumatoid, physical therapy for.** Sack KE. July 171.
- sexual relations, adjustment for.** Renshaw DC. Dec 89.
- Arthroscopy of knee.** Patel D. Sept 118.
- Asbestos and lung disease.** Greenberg SD. Aug 37.
- Asthma, Physicians' questions (10).** Falliers CJ. Nov 233.
- theophylline in management.** Wyatt RA. May 124.
- Athletics.** See **Sports.**
- Azoospermia, is it correctable? (Brief Consultation).** Cohen MS, Stewart BH. Feb 249.
- Back pain, low-back, radiologic guide to its myriad causes.** Sarokhan CT, Weissman BNW. Part 1, Nov 27; part 2, Dec 192.
- Bacteroides fragilis, microbiology update.** Bryan CS. May 207.
- Basketball injuries and the like, practical advice.** Apple DF Jr. Jan 71.
- Benzene.** See **Anemia, aplastic.**
- Biopsy, 'nonsurgical' techniques for lung disease.** Rhodes ML. June 61.
- Birth control.** See **Contraception.**
- Bladder tumors, current management of benign and malignant.** Oldani GO, Grabstald H. Feb 238.
- Bleeding, rectal, consider vascular ectasia.** Abel WG, Willner JS. Feb 223.
- rectal, gross.** See **Puzzling Cases, Why the gross rectal bleeding?**
- Blood pressure.** See **Hypertension.**
- Bone loss.** See **Osteoporosis.**
- Bowel disease, small-bowel obstruction: think of it early.** Lamphier TA. Jan 165.
- Breast cancer.** See **Cancer.**
- Brief Consultations:**
- Azoospermia, is it correctable?** Cohen MS, Stewart BH. Feb 249.
- Circumcision of the clitoris?** Renshaw D, Leif HI. March 167.
- Epilepsy, employment guidelines.** Engel J Jr, Goldensohn E. Oct 177.
- G.I. pain of no apparent cause.** Spiro H, Bynum TE. Nov 163.
- Hashimoto's thyroiditis.** Hamburger JI. Aug 173.
- Hypokalemia management.** Knochel JP. Sept 201.
- Mastectomy follow-up.** Urban JA, Schwartz GF. March 143.
- Orthostatic hypotension.** Rakita L. June 127.
- Pacemaker implantation, who should do.** Cohen LS, Thomas KE, Maloy WC. Oct 285.
- Patient who didn't get well (aplastic anemia from 'gun oil,' benzene compound).** Schwartz SO. Aug 158.
- Postinfarction arrhythmias.** Kinlaw WB. May 205.
- Postinfarction symptoms, managing.** Kinlaw WB. Feb 293.
- Postmenopausal estrogen replacement?** Gordan GS. May 50.
- Radiation exposure and lymphoid malignancy.** Marks AR. Nov 89.
- TB screening of hospital employees, ins and outs.** Bobrowitz ID. Feb 211.
- Burns, early care, establishing priorities.** Pruitt BA Jr. Nov 192.
- hands and arms.** Sandzen SC. Part 1, Sept 142; part 2, Oct 77.
- Bypass.** See **Coronary bypass.**
- Caesarean deliveries, why so many—are they justified?** Petrie RH, Gimovsky ML. Jan 88.
- Cancer, bladder tumors, current management of benign and malignant.** Oldani GO, Grabstald H. Feb 238.
- breast, adjuvant chemotherapy.** Carter SK. Sept 51.
- breast, disseminated, endocrine therapy.** Gordan G, Vaughan C. Nov 141.
- breast lumps, primary care approach.**

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- Adult respiratory distress syndrome.** See **Respiratory diseases.**
- Agoraphobia.** See **Clinical Cases** No. 80, April 262.
- Alcohol and medications, interactions.** Calesnick B. Aug 193.
- Alcoholism, and hard-drug dependency among physicians, a compassionate approach.** Cruse J. Nov 297.
- meeting head-on; the subtler side.** Whitfield CL. May 81; June 101.
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- Allergies, allergic dermatitis, complications and management.** Vander Ploeg DE. Sept 65.
- allergic urticaria.** Prawer SE, Katz HI, Hien NT. Feb 265.
- poison ivy rash? maybe, maybe not.** Schorr WF. July 37.
- Aminoglycosides.** See **Drugs.**
- Anemia, aplastic, from 'gun oil,' benzene compound (Brief Consultation).** Schwartz SO. Aug 158.
- iron deficiency in adolescents.** Lanzkowsky P. Aug 164.
- See also **Puzzling Cases** Woman with anemia.**
- Angioedema, better treatment in sight.** Sheffer AL. Sept 173.
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- Antiarrhythmic drugs.** See **Drugs.**
- Antibiotics.** See **Drugs.**
- Antihypertensive drugs.** See **Drugs.**
- Anti-inflammatory drugs.** See **Drugs.**
- Antiparasitic drugs.** See **Drugs.**
- Anxiety.** See **Clinical Cases** No. 80, April 262.
- Aortic valve disease.** See **Heart.**
- APGAR questionnaire, helping treat 'whole' patients.** Milkstein G. March 170.
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- postinfarction (Brief Consultation).** Kinlaw WB. May 205.
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- Arthritis, nonsteroidal anti-inflammatory drugs, which to use?** Pope RM. Feb 29.
- psoriatic, diagnostic dilemmas and therapeutic options.** Namey TC. Oct 236.
- rheumatic syndromes, diagnosing short-lived, self-limited.** Healey LA. Aug 97.
- rheumatoid, physical therapy for.** Sack KE. July 171.
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- Asthma, Physicians' questions (10).** Falliers CJ. Nov 233.
- theophylline in management.** Wyatt RA. May 124.
- Athletics.** See **Sports.**
- Azoospermia, is it correctable? (Brief Consultation).** Cohen MS, Stewart BH. Feb 249.
- Back pain, low-back, radiologic guide to its myriad causes.** Sarokhan CT, Weissman BNW. Part 1, Nov 27; part 2, Dec 192.
- Bacteroides fragilis, microbiology update.** Bryan CS. May 207.
- Basketball injuries and the like, practical advice.** Apple DF Jr. Jan 71.
- Benzene.** See **Anemia, aplastic.**
- Biopsy, 'nonsurgical' techniques for lung disease.** Rhodes ML. June 61.
- Birth control.** See **Contraception.**
- Bladder tumors, current management of benign and malignant.** Oldani GO, Grabstald H. Feb 238.
- Bleeding, rectal, consider vascular ectasia.** Abel WG, Willner JS. Feb 223.
- rectal, gross.** See **Puzzling Cases, Why the gross rectal bleeding?**
- Blood pressure.** See **Hypertension.**
- Bone loss.** See **Osteoporosis.**
- Bowel disease, small-bowel obstruction: think of it early.** Lamphier TA. Jan 165.
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- Brief Consultations:**
- Azoospermia, is it correctable?** Cohen MS, Stewart BH. Feb 249.
- Circumcision of the clitoris?** Renshaw D, Leif HI. March 167.
- Epilepsy, employment guidelines.** Engel J Jr, Goldensohn E. Oct 177.
- G.I. pain of no apparent cause.** Spiro H, Bynum TE. Nov 163.
- Hashimoto's thyroiditis.** Hamburger JI. Aug 173.
- Hypokalemia management.** Knochel JP. Sept 201.
- Mastectomy follow-up.** Urban JA, Schwartz GF. March 143.
- Orthostatic hypotension.** Rakita L. June 127.
- Pacemaker implantation, who should do.** Cohen LS, Thomas KE, Maloy WC. Oct 285.
- Patient who didn't get well (aplastic anemia from 'gun oil,' benzene compound).** Schwartz SO. Aug 158.
- Postinfarction arrhythmias.** Kinlaw WB. May 205.
- Postinfarction symptoms, managing.** Kinlaw WB. Feb 293.
- Postmenopausal estrogen replacement?** Gordan GS. May 50.
- Radiation exposure and lymphoid malignancy.** Marks AR. Nov 89.
- TB screening of hospital employees, ins and outs.** Bobrowitz ID. Feb 211.
- Burns, early care, establishing priorities.** Pruitt BA Jr. Nov 192.
- hands and arms.** Sandzen SC. Part 1, Sept 142; part 2, Oct 77.
- Bypass.** See **Coronary bypass.**
- Caesarean deliveries, why so many—are they justified?** Petrie RH, Gimovsky ML. Jan 88.
- Cancer, bladder tumors, current management of benign and malignant.** Oldani GO, Grabstald H. Feb 238.
- breast, adjuvant chemotherapy.** Carter SK. Sept 51.
- breast, disseminated, endocrine therapy.** Gordan G, Vaughan C. Nov 141.
- breast lumps, primary care approach.**

- Leis HP Jr. Aug 128.
breast, physician's role in rehabilitation. Schwartz GF. Oct 162.
colon polyps, management the key to cancer prevention. Panish JF, Sherlock P. Oct 119.
gastric carcinoma. See **Puzzling Cases**, Has the ulcer recurred?
laboratory tests for. Nichols WS, Nakamura RM. June 131.
noninvasive G.I. laboratory tests for. Segal HL. Dec 101.
nutritional needs of patient. Livstone EN. April 175.
ovarian, differential diagnosis. Katz AR. Dec 27.
skin, common premalignant skin lesions. Bart BJ. March 146.
See also **Irradiation**.
Carcinoma. See **Cancer**.
Cardiac catheterization. See **Catheterization**.
Cardiology. See **Heart and Electrocardiograms**.
Cardiovascular disease, complications of diabetes mellitus. Wolinsky H. July 84.
diagnostic studies in coronary artery disease, physicians' questions (10). Berger BC, Brest AN. Aug 215.
See also **Coronary bypass and Shock**.
Cardiovascular drugs, new. Alexander S. June 73; Doherty JE. Dec 80.
Cataracts, latest in cataract therapy. Kolder H. April 147.
Catheterization, cardiac, for heart murmurs. Leaman DM, Zelis RF. May 138.
Centers for Disease Control (CDC), immunobiologic agents and antiparasitic drugs available from. Oct 217.
Cephalosporins. See **Drugs**.
Cerebrovascular disease, evaluation and management. Ellison JP. June 89.
Checkup, routine—what to screen for. Siegel F. Jan 27.
Chest pain. See **Puzzling Cases**, Man with recurrent chest pain.
Children, ketoacidosis in young insulin-dependent diabetics. Malone JL. July 176.
limp, cause. Gucker T 3rd. June 194.
pediatric hypertension, pharmacologic alternatives amid therapy controversy. Loggie JM¹. Oct 245.
vaccination for childhood diseases, changing views. Marcuse EK. Nov 271.
Chronic obstructive pulmonary disease. See **Clinical Cases** No. 81, May 174.
Circumcision of clitoris? (Brief Consultation). Renshaw D, Leif HI. March 167.
Clinical Cases:
No. 77, Jan 188. Woman with increasing dyspnea (pigeon breeder's disease). Sharma OP.
No. 78, Feb 254. Patient with fatigue, dyspnea, and palpitation (hypertrophic subaortic stenosis). Friedewald VE Jr.
No. 79, March 133. 'Doc, I think my ulcer has come back' (Zollinger-Ellison syndrome). Globor G.
No. 80, April 262. Woman with anxiety (panic anxiety, agoraphobia). Raskin DE.
No. 81, May 174. Middle-aged man with weakness and dyspnea (chronic obstructive pulmonary disease). Raffin TA.
No. 82, June 176. Young woman with cough and fever (tularemia). Diefenbach WCL.
No. 83, July 212. 'Food seems to stick halfway down' (reflux esophagitis). Gray JE.
No. 84, Aug 180. Man with generalized edema (nephrotic syndrome—nil lesion). Lifschitz MD.
No. 85, Sept 228. Woman with painful nodule (hidradenitis suppurativa). Glickman FS.
No. 86, Oct 222. Marathon runner with unusual weight loss (infective endocarditis). Daneshmandi RL, Cohen LS.
No. 87, Nov 204. Embarrassment of urinary incontinence (idiopathic detrusor instability). Fantl JA.
No. 88, Dec 158. 'Doctor, my asthma medication isn't working' (aspergillosis). Sharma OP.
Clitoris, circumcision? (Brief Consultation). Renshaw D, Leif HI. March 167.
Compliance, geriatric, probing obstacles. Walz TH, Williams GO. Oct 65.
hypertension, specially trained personnel can help improve. Finnerty FA Jr. March 80.
Contraception for adolescent girls. DeLa JE. March 63.
natural family planning. McCarthy JJ Jr. Dec 109.
which method and why? Weiss G. Nov 285.
Convulsions. See **Seizures**.
Coronary artery disease, diagnostic studies, physicians' questions (10). Berger BC, Brest AN. Aug 215.
Coronary bypass, does it prolong life? improve life quality? Hammermeister KE. June 154.
post-bypass exercise, restoring patients to active life. Oberman A. Nov 177.
who should have? Russell RO Jr, Rackley CE, Kouchoukos NT. Jan 121.
Cosmetics, what are the hazards? Fisher AA. Feb 172.
Dehydration. See **Hyperglycemic dehydration**.
Dermatitis, allergic, complications and management. Vander Ploeg DE. Sept 65.
and athletic activity. Levine N. Aug 114.
cosmetics, hazards of. Fisher AA. Feb 172.
cutaneous drug reactions. Odom RB, Berger TG. May 55.
periocular, how do you treat it? Frank SB. Jan 143.
poison ivy rash? maybe, maybe not. Schorr WF. July 37.
secondary to zoonoses. Burnett JW. Dec 137.
See also **Skin lesions and Urticaria**.
Diabetes, in elderly, neurologic problems, diagnosing. Ellenberg M. April 113.
in elderly, problems to watch for. Shuman CR. June 54.
exercise planning for insulin-dependent diabetics. Huff TA. Feb 71.
and hypertension, deadly duo. Tzagournis M. Sept 247.
infections in diabetic patients. Casey J. May 169.
insulin therapy, complications. Whitehouse FW. April 275.
ketoacidosis in diabetic patients, managing. Pagliara AS. March 121.
ketoacidosis in young insulin-dependent diabetics. Malone JL. July 176.
overweight diabetic patients: diets can work. Davidson JK. Jan 251.
and pregnancy. Iffy L. Aug 61.
preoperative considerations. Whitehouse FW. Dec 151.
and skin disorders, clues to unrecognized or uncontrolled disease. Roenigk HH Jr. Oct 136.
Diabetes mellitus and cardiovascular complications. Wolinsky H. July 84.
Diarrhea, chronic. See **Puzzling Cases**, Homosexual man with chronic diarrhea, physicians' questions (10). Farmer RG. May 23.
postoperative. See **Puzzling Cases**, Why the postoperative diarrhea?
Diet, overweight diabetic patients: diets can work. Davidson JK. Jan 251.
Digitalis therapy. See **Drugs**.
Dislocations, upper extremity, practical management. Howland WS Jr. Feb 183.
Diuretics for hypertension, which one? when? Vidt DG. April 242.
Diverticular disease, current medical management. Howell DA, Almy TP. Sept 160.
surgery indications. Jagelman DG. Oct 195.
Down's syndrome, reappraising treatment of children and adults. Deaton J. April 249.
Drugs and alcohol interactions. Calesnick B. Aug 193.
aminoglycosides, when and how to choose the 'proper' one. Lea AS, Williams TW Jr. July 27.
antiarrhythmic, new. Alexander S. Aug 107; Doherty JE. Dec 80.
antibiotics, rational selection for pneumonia. Griffin FM Jr. Jan 47. (See also "cephalosporin," below.)
antihypertensive, for children. Loggie JM¹. Oct 245.
antihypertensive, newer. Alexander S. July 135.
anti-inflammatory, nonsteroidal, which to use? Pope RM. Feb 29.
antiparasitic drugs and immunobiologic agents available from CDC. Oct 217.
cardiovascular, new. Alexander S. June 73.
cephalosporin, 'proper' one, when and how to choose. Williams TW Jr., Lea AS. April 101.
digitalis therapy, when and how to discontinue. Benditt DG. Feb 137.
diuretics for hypertension, which one? when? Vidt DG. April 242.
drug and device problems, reporting.

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Adverse Reactions: Usually dose-related and generally respond to reduction or withdrawal of therapy. Generally transient and not of a serious nature and include anorexia, nausea, vomiting and gastrointestinal intolerance; weakness and paresthesias. Certain untoward reactions associated with idiosyncrasy or hypersensitivity have occasionally occurred, including jaundice (rarely associated with severe diarrhea and bleeding), skin eruptions rarely progressing to erythema multiforme and exfoliative dermatitis, and probably depression of formed elements of the blood. With a few exceptions, these manifestations have been mild and readily reversible on the withdrawal of the drug. Diabinese should be discontinued promptly when the development of sensitivity is suspected. Jaundice has been reported, and is usually promptly reversible on discontinuance of therapy. THE OCCURRENCE OF PROGRESSIVE ALKALINE PHOSPHATASE ELEVATION SHOULD SUGGEST THE POSSIBILITY OF INCIPENT JAUNDICE AND CONSTITUTES AN INDICATION FOR WITHDRAWAL OF THE DRUG.

Leukopenia, thrombocytopenia and mild anemia, which occur occasionally, are generally benign and revert to normal, following cessation of the drug.

Cases of aplastic anemia and agranulocytosis, generally similar to blood dyscrasias associated with other sulfonylureas, have been reported.

BECAUSE OF THE PROLONGED HYPOLYCEMIC ACTION OF DIABINESE, PATIENTS WHO BECOME HYPOLYCEMIC DURING THERAPY WITH THIS DRUG REQUIRE CLOSE SUPERVISION FOR A MINIMUM PERIOD OF 3 TO 5 DAYS, during which time frequent feedings or glucose administration are essential. The anorectic patient or the profoundly hypoglycemic patient should be hospitalized.

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YEAR-END INDEX

- Oct 280.
for elderly, playing it safe. Nattel S. Sept 87.
hard-drug dependency and alcoholism among physicians, a compassionate approach. Cruse J. Nov 297.
and pregnancy. Goplerud CP. April 29.
protein binding doesn't have to interfere with therapy. Reidenberg MM. July 59.
quinidine, a new look at a vintage antiarrhythmic drug. Carliner NH, Fisher ML. Nov 256.
skin eruptions caused by. Odom RB, Berger TG. May 55.
theophylline in asthma management. Wyatt RA. May 124.
tranquilizers, major, manual for nonpsychiatrists. DiGiacomo JN. Nov 68.
warfarin, interactions with other drugs, clinically important. Bailey RE. April 281.
See also **Alcoholism**.
- Dysphagia.** See **Clinical Cases** No. 83, July 212.
- Dysplasia.** See **Puzzling Cases**, Why the gross rectal bleeding?
- Dyspnea.** See **Clinical Cases** No. 77, Jan 188; No. 78, Feb 254; No. 81, May 147.
- ECGs.** See **Electrocardiograms**.
- Ectasia.** See **Vascular ectasia**.
- Edema.** See **Angioedema and Clinical Cases** No. 84, Aug 180.
- Editorial opinion:**
Murata SK:
Clinical pearls and you. April 288.
Clinical significance of patent life. Sept 256.
Cost containment and the indivisibility of the patent. Feb 294.
Patient Package Inserts—aren't there better solutions? March 224.
Schwartz L:
Generic substitution: where have all the experts gone? Oct 290.
- Elbow,** pitcher's elbow in adolescents. Grana WA. June 33.
- Elderly,** and compliance, probing obstacles. Walz TH, Williams GO. Oct 65.
diabetic patients, neurologic problems, diagnosing. Ellenberg M. April 113.
diabetic patients, problems to watch for. Shuman CR. June 54.
drugs, playing it safe. Nattel S. Sept 87.
infections, understanding and treating. Palmer DL. Aug 201.
- Electrocardiograms,** unusual, in patients without heart disease. Witham AC. April 193.
use in ventricular hypertrophy. Canedo MI. July 155.
- Electrolytes,** hypernatremia, misunderstood and dangerous. Whittier FC. June 206.
- Electromyography,** how it helps and when. Smith LJ, Calverley JR. Sept 213.
- Embolism.** See **Thrombosis**.
- Emergencies.** See **Burns; Hepatic failure; Respiratory diseases, adult respiratory distress syndrome; Screening, evaluation of trauma. Encephalopathy, hypertensive. Ram CVS.** Jan 177.
- Endocarditis,** infective: a challenging and changing disease. Harper JF, Steelman RB. April 43.
See also **Clinical Cases** No. 86, Oct 222.
- Endocrine therapy** for disseminated breast cancer. Gordan G, Vaughan C. Nov 141.
- Enterobacteriaceae,** microbiology update. Bryan SC. March 193.
- Epilepsy.** See **Seizures**.
- Esophageal spasm.** See **Puzzling Cases**, Man with recurrent chest pain.
- Esophagitis.** See **Clinical Cases** No. 83, July 212.
- Estrogen replacement,** postmenopausal (Brief Consultation). Gordan GS. May 50.
- Exercise,** and heart disease, perspective on new findings. Hartung GH, Gotto AM. Oct 52.
for insulin-dependent diabetics. Huff TA. Feb 71.
post-bypass, restoring patients to active life. Oberman A. Nov 177.
- Eyes.** See **Cataracts**.
- Family APGAR questionnaire,** helping treat 'whole' patients. Smilkstein G. March 170.
- Family 'health.'** See **Family APGAR questionnaire**.
- Fatigue,** adolescent. Melnick A. July 150.
See also **Clinical Cases** No. 78, Feb 254.
- Foot problems.** See **Limp**.
- Fractures,** broken nose, management. Maisel RH. May 74.
- Gallbladder,** newer ways of looking at liver, gallbladder, and pancreas. Kleinman MS. April 71.
- Gallstones,** silent: screening for high-risk persons. Tangedahl TN, Dyck WP. Feb 113.
- Gastrointestinal disorders,** abdominal pain. See **Brief Consultations, G.I.** pain of no apparent cause; **Puzzling Cases**, Unexplained abdominal pain.
cancer, noninvasive tests for. Segal HL. Dec 101.
chronic pancreatitis, surgery—when and what kind? Cooperman AM. Feb 163.
colon polyps, management the key to cancer prevention. Panish JF, Sherlock P. Oct 119.
diverticular disease, current medical management. Howell DA, Almy TP. Sept 160.
diverticular disease, surgery indications. Jagelman DG. Oct 195.
gastric carcinoma. See **Puzzling Cases**, Has the ulcer recurred?
gastric ulcer, physicians' questions (10). Flesher B. Dec 68.
irritable bowel syndrome. Legerton CW. June 25.
nausea: what does it signal? Wolf S. Aug 27.
protein-losing enteropathies: 'hidden disease.' Schwabe AD. March 111.
rectal bleeding, consider vascular ectasia. Abel WG, Willner JS. Feb 223.
rectal bleeding, gross. See **Puzzling Cases**, Why the gross rectal bleeding?
rectal polyps, what you can do. Kraft

YEAR-END INDEX

- SC. April 219.
small-bowel obstruction: think of it early. Lamphier TA. Jan 165.
See also **Diarrhea**, **Gallbladder**, and **Gallstones**.
- Genital herpesvirus**. See **Herpesvirus**.
- Geriatrics**. See **Elderly**.
- Giant cell arteritis**, occult. Healey LA Jr. July 227.
- Giardiasis**. See **Puzzling Cases**, Homosexual man with chronic diarrhea.
- Gonococcal sepsis**, mimics other disorders. Williams RC Jr. Sept 222.
- 'Gun oil.'** See **Anemia**, aplastic.
- Hand injuries**, burns of hands and arms. Sandzen SC. Part 1, Sept 142; part 2, Oct 77.
primary care. McCoy JR, Weber ER. April 126.
- Headaches**, chronic tension, helping patients overcome. Friedman AP. June 147.
migraine, treating severe and complicated. Diamond S, Medina JL. Jan 131.
organic and systemic causes. Friedman AP. March 205.
- Hearing loss**, acoustic nerve tumors, what to do about. Gacek RR. July 110.
how you can help patients with hearing problems. Katz AE. Jan 38.
- Heart**, antiarrhythmic drugs, new. Alexander S. Aug 107.
antiarrhythmic drugs, new. Doherty JE. Dec 80.
antihypertensive drugs for children. Loggie JNH. Oct 245.
antihypertensive drugs, newer. Alexander S. July 135.
aortic valve disease: changing concepts of aortic stenosis (part 1); understanding aortic regurgitation (part 2). Gregoratos G. Jan 60; Feb 87.
arrhythmias of acute myocardial infarction, treating. Biddle LT. March 38.
arrhythmias, postinfarction (Brief Consultation). Kinlaw WB. May 205.
coronary bypass, does it prolong life? improve life quality? Hammermeister KE. June 154.
coronary bypass, exercise after. Oberman A. Nov 177.
coronary bypass, who should have? Russell RO Jr, Rackley CE, Kouchoukos NT. Jan 121.
digitalis therapy, when and how to discontinue. Benditt DG. Feb 137.
ECGs, unusual, in patients without heart disease. Witham AC. April 193. (See also "ventricular hypertrophy" below.)
exercise and heart disease, perspective on new findings. Hartung GH, Gotto AM. Oct 52.
hypertrophic subaortic stenosis. See **Clinical Cases** No. 78, Feb 254.
infective endocarditis: a challenging and changing disease. Harper JF, Steelman RB. April 43.
infective endocarditis. See **Clinical Cases** No. 86, Oct 222.
mitral regurgitation. Chahine RA, Verani MS. Sept 129. (See also **Clinical Cases** No. 86, Oct 222.)
murmurs, cardiac catheterization. Leaman DM, Zelis RF. May 138.
myocardial infarction: the silent menace. Coodley EL. May 44.
pacemaker implantation, who should do (Brief Consultation). Cohen LS, Thomas KE, Maloy WC. Oct 285.
postinfarction symptoms, managing (Brief Consultation). Kinlaw WB. Feb 293.
tachyarrhythmias, refractory, marshalling old and new weapons. Cohen SI. Oct 107.
ventricular hypertrophy, using ECG to zero in on. Canedo MI. July 155.
ventricular premature contractions, how to manage. Cohen LS. July 96.
See also **Hypertension**, **Hypotension**, and **Shock**.
- Hemophilus influenzae**. See **Influenza**.
- Hemorrhagic shock**. See **Shock**.
- Hepatic failure**, fulminant, can be life-threatening. Berk PD. March 182.
- Hepatitis**, chronic, many disease forms, varied remedies. Nagel P, Winter SL. Nov 48.
non-A, non-B, similarities to hepatitis A and B. Achord JL. Jan 204.
viral: diagnosis, hospitalization, precautions. Izsak EM. Feb 155.
- Herpes zoster**, preventing post-herpetic pain. Raj PP. March 71.
- Herpesvirus**, genital, managing. Curolle DN. June 47.
- Hidradenitis suppurativa**. See **Clinical Cases** No. 85, Sept 228.
- Hip pain**, cause. Schottenfeld M. Aug 47.
- Hives**. See **Urticaria**.
- HL-A markers**, promise of. Dwyer JM. June 111.
- Homosexuality**. See **Puzzling Cases**, Homosexual man with chronic diarrhea.
- Hospital employees**, TB screening, ins and outs (Brief Consultation). Bobrowitz ID. Feb 211.
- Hyperglycemic dehydration**, swift but thorough approach to subtle disorder. Lueg MC. Nov 91.
- Hypernatremia**, misunderstood and dangerous. Whittier FC. June 206.
- Hypertension**, antihypertensive drugs, newer. Alexander S. July 135.
compliance, specially trained personnel can help improve. Finnerty FA Jr. March 80.
and diabetes, deadly duo. Tzagournis M. Sept 247.
diuretics, which one? when? Vidt DG. April 242.
hypertensive encephalopathy. Ram CVS. Jan 177.
kidney conditions as cause. Krumlovsky FA, Ginsburg D. Aug 140.
mild, diagnosis and management. Taylor AA. May 225.
pediatric, pharmacologic alternatives amid therapy controversy. Loggie JMH. Oct 245.
and pregnancy, guiding patient toward safe delivery. Stenchever MA. Nov 82.
primary aldosteronism. Ram CVS. Dec 211.
resistant, identifying and treating. Gifford RW Jr. June 220.
- Hypertrophic subaortic stenosis**. See **Clinical Cases** No. 78, Feb 254.
- Hypokalemia**, managing (Brief Consultation). Knochel JP. Sept 201.
- Hypotension**, orthostatic (Brief Consultation). Rakita L. June 217.
- Immune system**, defects, how to evaluate. Mandell GL. March 55.
HL-A markers, promise of. Dwyer JM. June 111.
- Immunization**. See **Vaccination**.
- Immunobiologic agents**, and antiparasitic drugs available from CDC. Oct 217.
- Infections**, aspergillosis. See **Clinical Cases** No. 88, Dec 158.
Bacteroides fragilis, microbiology update. Bryan CS. May 207.
in diabetic patients. Casey J. May 169.
in elderly, understanding and treating. Palmer DL. Aug 201.
Enterobacteriaceae. Bryan CS. March 193.
hepatitis, non-A, non-B, similarities to hepatitis A and B. Achord JL. Jan 204.
hepatitis, viral: diagnosis, hospitalization, precautions. Izsak EM. Feb 155.
immune system defects as cause. Mandell GL. March 55.
infective endocarditis: a challenging and changing disease. Harper JF, Steelman RB. April 43.
infective endocarditis, marathon runner with weight loss. See **Clinical Cases** No. 86, Oct 222.
influenza and pneumonia, vaccination recommendations. Palmer DL. Oct 29.
Hemophilus influenzae, microbiology update. Bryan CS. Feb 229.
meningococcus, microbiology update. Bryan CS. Jan 101.
parasitic. See **Toxoplasmosis**.
pilonidal, current management. Christensen MA. April 184.
pneumonia. Heineman HS. Dec 49.
Pseudomonadaceae. Bryan CS. April 163.
trichinosis, forgotten but not gone. Most H. Sept 101.
urinary tract, newest thinking. Krieger JN, Mandell GL. April 224.
vaginal, diagnosing and treating. Fiumara NJ. Feb 281.
See also specific subjects.
- Influenza**. *Hemophilus influenzae*, microbiology update. Bryan CS. Feb 229.
and pneumonia, vaccination recommendations. Palmer DL. Oct 29.
- Insomnia**, rational approach. Roth T, Zorick F. Oct 203.
- Insulin therapy**, complications. Whitehouse FW. April 275.
- Iron deficiency**. See **Anemia**.
- Irradiation** and lymphoid malignancy (Brief Consultation). Marks AR. Nov 89.
- Irritable bowel syndrome**, current thinking on. Legerton CW. June 25.
- Jaundice**, no longer an enigma. Black M. July 120.
- Joint injuries**, hand, primary care. McCoy JR, Weber ER. April 126.
hip pain, cause. Schottenfeld M.

PNU-IMUNE®

Pneumococcal Vaccine, Polyvalent

INDICATIONS

PNU-IMUNE is indicated for immunization against pneumococcal disease caused by those pneumococcal types included in the vaccine. See package circular for full prescribing details.

Simultaneous administration of pneumococcal polysaccharide vaccine and whole-virus influenza vaccine has been found to give satisfactory antibody response without increasing the incidence of side effects. Although not yet studied, simultaneous administration of the pneumococcal vaccine and split-virus influenza vaccine may also be expected to yield satisfactory results.

CONTRAINDICATIONS

Pregnancy: Safety, immunogenicity and efficacy of the vaccine in pregnancy has not been established, and vaccination is not recommended during pregnancy.

Children Below 2 Years of Age: Children in this age group respond poorly to the current vaccine, and vaccination of children in this age group should not be undertaken.

Hypersensitivity: Known hypersensitivity to any component of the vaccine, including hypersensitivity to thimerosal. Remedial measures for anaphylactoid reactions, including epinephrine injection (1:1000), must be available for immediate use.

WARNINGS:

PNU-IMUNE is not an effective agent for prophylaxis against pneumococcal disease caused by types not present in the vaccine. The vaccine may not be effective in patients undergoing treatment causing therapeutic suppression of the immune-response system.

Patients who have received extensive chemotherapy and/or splenectomy for the treatment of Hodgkin's Disease have been shown to have an impaired serum antibody response to pneumococcal vaccine.

PRECAUTIONS

The vaccine should be injected deeply subcutaneously or intramuscularly. Do not inject intravenously. In the presence of any febrile respiratory illness or other active infection, the vaccine should not be used. The parenteral administration of any biological product should be surrounded by every known precaution for the prevention and arrest of allergic and other untoward reactions. A separate heat-sterilized syringe and needle or a new disposable equivalent should be used for each patient to prevent transmission of hepatitis B or other infectious agents. Patients having had episodes of pneumococcal pneumonia or other pneumococcal infection in the preceding three years may have high levels of pre-existing pneumococcal antibodies, which may result in increased reactions to PNU-IMUNE, mostly local but occasionally systemic. Exercise caution if such patients are considered for vaccination with PNU-IMUNE. Revaccination should not be considered at less than 5-year intervals, since protective antibody levels are believed to persist for substantial periods in most vaccinated persons. Revaccination before 5 years may result in more frequent and severe local reactions at the site of injection, especially in persons who have retained high antibody levels.

ADVERSE REACTIONS

Adverse reactions with PNU-IMUNE are relatively few, not serious, and of short duration, consisting for the most part of local reaction at injection site within 3 days after vaccination, low grade fever (less than 100°F), usually confined to the 24-hour period following vaccination. Although rare, fever over 102°F and marked local swelling have been reported with pneumococcal polysaccharide vaccine. Reactions of greater severity or extent are unusual. Rarely, anaphylactoid reactions have been reported.



LEDERLE LABORATORIES,
A Division of American Cyanamid Company,
Wayne, New Jersey 07470

YEAR-END INDEX

- Aug 47.
knee, arthroscopy. Patel D. Sept 118.
knee, 'Doctor, my knee keeps going out on me.' Leach RE. May 152.
knee, how severe? Reckling FW. Jan 233.
upper extremity dislocations, practical management of. Howland WS Jr. Feb 183.
wrist, primary care. Clark JM, Matsen FA. Sept 38.
Ketoacidosis, in diabetic patients, managing. Pagliara AS. March 121.
in young insulin-dependent diabetics. Malone JJ. July 176.
Kidney and hypertension. Krumlovsky FA, Ginsburg D. Aug 140.
Knee. See Joint injuries.
Laboratory tests. See Tests.
Lactic acidosis, what's the underlying cause? Groshong T. May 114.
Leg problems. See Ankle ligament injuries and Limp.
Ligament injuries. See Ankle ligament injuries.
Limp, in adolescents and children, cause. Gucker T 3rd. June 194.
Liver, jaundice—no longer an enigma. Black M. July 120.
newer ways of looking at liver, gallbladder, and pancreas. Kleinman MS. April 71.
nutritional therapy and the liver: benefit and risk. Riely CA. May 194.
See also **Hepatic failure and Hepatitis.**
Lung disease. See Respiratory diseases.
Mastectomy follow-up (Brief Consultation). Urban JA, Schwartz GF. March 143.
Measles, new and changing aspects of rubeola. Frenkel LD. Feb 94.
Menarche, delayed, causes and management. Bongiovanni AM. July 53.
Meningitis, bacterial, disease of young and old. Yoshikawa TT, Norman DC. Nov 219.
nonbacterial. Yoshikawa TT, Norman DC. Dec 175.
Meningococcus, microbiology update. Bryan CS. Jan 101.
Menopause. See Estrogen replacement.
Menses. See Premenstrual tension.
Mental retardation. See Down's syndrome.
Metabolism. See Lactic acidosis.
Michigan Alcoholism Screening Test. May 86.
Microbiology lab, using, why and when? Heineman HS. May 101.
Microbiology update, 'new faces of old enemies' (series of 8). Bryan CS. Meningococcus, Jan 101; Hemophilus influenzae, Feb 229; Enterobacteriaceae, March 193; Pseudomonadaceae, April 163; Bacteroides fragilis, May 207.
In 1980: pneumococcus, Oct 159; streptococcus, Nov 33; staphylococcus, Dec 83.
Migraine, treating severe and complicated. Diamond S, Medina JL. Jan 131.
Mitral regurgitation, a primer. Chahine RA, Verani MS. Sept 129.
See also **Clinical Cases** No. 86, Oct 222.
Murmurs, cardiac catheterization. Leaman DM, Zelis RF. May 138.
Musculoskeletal pain. See Polymyalgia rheumatica.
Myocardial infarction, acute, treating arrhythmias. Biddle TL. March 38.
Myocardial pathology: the silent menace. Coodley EL. May 44.
Narcolepsy, and sleep apnea, recognition and management. Orr WC. Feb 202.
Nasopharyngeal complications. See Postnasal drip.
Nausea, what does it signal? Wolf S. Aug 27.
Nephrotic syndrome. See Clinical Cases No. 84, Aug 180.
Nerve tumors, acoustic, what to do about. Gacek RR. July 110.
Neurologic problems in elderly diabetic patients, diagnosing. Ellenberg M. April 113.
Neuromuscular studies. See Electromyography.
Nil lesion. See Clinical Cases No. 84, Aug 180.
Noncompliance, 8 steps for improving patient cooperation. Skillern PG. July 206.
what do we really know about? Blackwell B. Jan 259.
Nose, broken, management. Maisel RH. May 74.
stuffy, companion to many disorders. Mabry RL. Sept 29.
Nutrition, needs of cancer patient. Livstone EM. April 175.
nutritional therapy and the liver: benefit and risk. Riely C. May 194.
Obesity, dispelling some hormonal and nutritional myths. Rivlin RS. June 125.
and surgery. Wachtel TJ. Aug 123.
Occupational hazards, asbestos and lung disease. Greenberg SD. Aug 37.
Opinion. See Editorial.
Osteoporosis, understanding and treating. Baran DT. April 57.
Overseas service. See Volunteer service.
Pacemaker implantation, who should do (Brief Consultation). Cohen LS, Thomas KE, Maloy WC. Oct 285.
Pain, chronic, physicians' questions (10). Murphy TM. March 27.
chronic abdominal pain (Brief Consultation). Spiro H, Bynum TE. Nov 163.
See also **Back pain and Polymyalgia rheumatica.**
Palpitation. See Clinical Cases No. 78, Feb 254.
Pancreas, newer ways of looking at liver, gallbladder, and pancreas. Kleinman MS. April 71.
Pancreatitis, chronic, surgery—when and what kind? Cooperman AM. Feb 163.
Panic. See Clinical Cases No. 80, April 262.
Parasites. See Toxoplasmosis.
Parenteral nutrition. See Liver.
Patient aids, handy warm-up and muscle stretching guide. Apple DF Jr. Jan 84.
Pediatric illness. See Children.
Pets. See Zoonoses.
Photoclinic. Jan 149; Feb 195; March 159; April 155; May 133; June 141; July 145; Aug 153; Sept 167; Oct 169; Nov 169; Dec 125.

THEOLAIR™ TABLETS
(theophylline) 125 mg 250 mg

THEOLAIR™ LIQUID
(theophylline) 80 mg per 15 ml

THEOLAIR™-SR TABLETS
(theophylline) 250 mg 500 mg

Brief Summary

INDICATIONS: For relief of acute bronchial asthma and for reversible bronchospasm associated with chronic bronchitis and emphysema.

CONTRAINDICATIONS: In individuals who have shown hypersensitivity to any of its components.

WARNINGS: Status asthmaticus is a medical emergency. Optimal therapy frequently requires additional medication including corticosteroids when the patient is not rapidly responsive to bronchodilators.

Excessive theophylline doses may be associated with toxicity and serum theophylline levels are recommended to assure maximal benefit without excessive risk. Incidence of toxicity increases at levels greater than 20 µg/ml. Morphine, curare, and stilbamidine should be used with caution in patients with airflow obstruction since they stimulate histamine release and can induce asthmatic attacks. They may also suppress respiration leading to respiratory failure. Alternative drugs should be chosen whenever possible. There is an excellent correlation between high blood levels of theophylline resulting from conventional doses and associated clinical manifestations of toxicity in (1) patients with lowered body plasma clearances (due to transient cardiac decomposition), (2) patients with liver dysfunction or chronic obstructive lung disease, (3) patients who are older than 55 years of age, particularly males. There are often no early signs of less serious theophylline toxicity such as nausea and restlessness, which may appear in up to 50 percent of patients prior to onset of convulsions. Ventricular arrhythmias or seizures may be the first signs of toxicity. Many patients who have higher theophylline serum levels exhibit a tachycardia.

Theophylline products may worsen pre-existing arrhythmias.

USAGE IN PREGNANCY: Safe use in pregnancy has not been established relative to possible adverse effects on fetal development, but neither have adverse effects on fetal development been established. This is unfortunately true for most antiasthmatic medications. Therefore, use of theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

PRECAUTIONS: Mean half-life in smokers is shorter than in nonsmokers; therefore smokers may require larger doses of theophylline. Theophylline should not be administered concurrently with other xanthine medications. Use with caution in patients with severe cardiac disease, severe hypoxemia, hypertension, hyperthyroidism, acute myocardial injury, cor pulmonale, congestive heart failure, liver disease, and in the elderly (especially males) and in neonates. Great caution should especially be used in giving theophylline to patients in congestive heart failure. Such patients have shown markedly prolonged theophylline blood level curves with theophylline persisting in serum for long periods following discontinuation of the drug.

Use theophylline cautiously in patients with history of peptic ulcer.

Theophylline may occasionally act as a local irritant to G.I. tract although gastrointestinal symptoms are more commonly central and associated with serum concentrations over 20 µg/ml.

ADVERSE REACTIONS: The most consistent adverse reactions are usually due to overdose and are:

1. Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea.
2. Central nervous system: headaches, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions.
3. Cardiovascular: palpitation, tachycardia, extra systoles, flushing, hypotension, circulatory failure, life threatening ventricular arrhythmias.
4. Respiratory: tachypnea.
5. Renal: albuminuria, increased excretion of renal tubular potentiation or diuresis, and red blood cells.
6. Others: hyperglycemia and inappropriate ADH syndrome.

DRUG INTERACTIONS: Toxic synergism with epinephrine has been documented and may occur with some other sympathomimetic bronchodilators.

DRUG	EFFECT
Aminophylline with Lithium Carbonate	Increased excretion of Lithium Carbonate
Aminophylline with Propranolol	Antagonism of Propranolol effect
Theophylline with Furosemide	Increased diuresis of Furosemide
Theophylline with Hexamethonium	Decreased Hexamethonium-induced chromatographic effect
Theophylline with Reserpine	Reserpine-induced tachycardia
Theophylline with Chlorthalidopoxide	Chlorthalidopoxide-induced fatty acid mobilization
Theophylline with Cycloamin (TAO = Triacetyl-tolendomylin): erythromycin, lincomycin	Increased Theophylline plasma levels

CAUTION: Federal (USA) Law prohibits dispensing without prescription.

THEO-8A

THEOLAIR™-PLUS 125 TABLETS
(theophylline, 125 mg; guaifenesin, 100 mg)

THEOLAIR™-PLUS 250 TABLETS
(theophylline, 250 mg; guaifenesin, 200 mg)

THEOLAIR™-PLUS LIQUID
(theophylline, 125 mg; guaifenesin, 100 mg per 15 ml)

Brief Summary

INDICATIONS AND USAGE: Theolair-Plus is indicated for the symptomatic treatment of bronchospasm associated with such conditions as bronchial asthma, chronic bronchitis and pulmonary emphysema.

CONTRAINDICATIONS: Theolair-Plus is contraindicated in individuals who have shown hypersensitivity to any of its components or xanthine derivatives.

WARNINGS: Excessive theophylline doses may be associated with toxicity; thus serum theophylline levels should be monitored to assure maximal benefit without excessive risk. Serum levels of theophylline above the accepted therapeutic range (10-20 µg/ml) are associated with an increased incidence of toxicity.

Such levels may be reached with customary doses in individuals who metabolize the drug slowly, especially patients (1) with lowered body plasma clearance, (2) with liver dysfunction or chronic obstructive pulmonary disease, (3) older than 55 years of age, particularly males.

Serious toxicity, such as seizure or ventricular arrhythmias, is not necessarily preceded by less serious side effects such as nausea, irritability or restlessness. Many patients who have higher (greater than 20 µg/ml) theophylline serum levels exhibit a tachycardia. Theophylline products may exacerbate pre-existing arrhythmias.

PRECAUTIONS:

General: Theophylline. Use with caution in patients with severe cardiac disease, hypertension, acute myocardial injury, congestive heart failure, cor pulmonale, severe hypoxemia, hyperthyroidism, hepatic impairment, history of peptic ulcer, alcoholism and in the elderly. Concurrent administration with certain antibiotics (troleandomycin, erythromycin, clindamycin) may result in increased serum theophylline levels.

General: Guaifenesin. Plasma prothrombin and factor V may increase, but any resulting clinical effect is likely to be small.

Drug Interactions:

Drug	Effect
Theophylline with furosemide	Increased diuresis
Theophylline with reserpine	Tachycardia
Theophylline with chlorthalidopoxide	Fatty acid mobilization
Theophylline with troleandomycin, erythromycin, or clindamycin	Increased theophylline plasma level

Drug/Laboratory Test Interactions: Theophylline may increase uric acid levels and urinary catecholamines. Metabolites of guaifenesin may contribute to increased urinary 5-hydroxy-indoleacetic acid readings, when determined with nitrosonaphthol reagent. Long-Term Carcinogenic Studies: No animal studies have been conducted with Theolair-Plus products.

USAGE IN PREGNANCY:

Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Theolair-Plus products. It is also not known whether Theolair-Plus products can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Theolair-Plus products should be given to a pregnant woman only if clearly indicated.

Nonteratogenic Effects: It is not known whether use of this drug during labor or delivery has immediate or delayed adverse effects on the fetus, or whether it prolongs the duration of labor or increases the possibility of forceps delivery or other obstetrical intervention. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Theolair-Plus products are administered to a nursing woman.

ADVERSE REACTIONS: The frequency of adverse reactions is related to serum theophylline levels and is usually not a problem at levels below 20 µg/ml. The most consistent adverse reactions are usually due to overdose and, while all have not been reported with Theolair-Plus, the following reactions may be considered when theophylline is administered. Central nervous system: clonic and tonic generalized convulsions, muscle twitching, reflex hyperexcitability, headaches, insomnia, restlessness, and irritability. Cardiovascular: circulatory failure, ventricular arrhythmias, hypotension, extra systoles, tachycardia, palpitation, and flushing. Gastrointestinal: hematemesis, vomiting, diarrhea, epigastric pain, and nausea. Renal: increased excretion of renal tubular cells and red blood cells, albuminuria, and diuresis. Respiratory: tachypnea. Others: hyperglycemia and inappropriate ADH syndrome.

CAUTION: Federal (USA) Law prohibits dispensing without prescription.

THEO-PLI

Riker Laboratories, Inc.
Northridge, California 91324



Photo feature, stigma of syphilis.
Jan 244.

Physical exam, routine checkup—what to screen for. Siegel F. Jan 27.
spirometry in office, part of routine physical exam. Cherniack R. Oct 187.

Physical therapy for rheumatoid arthritis. Sack KE. July 171.

Physicians, alcoholism and hard-drug dependency, a compassionate approach. Cruse J. Nov 297.

Physicians' questions. See Questions physicians often ask . . .

Pigeon breeder's disease. See Clinical Cases No. 77, Jan 188.

Pilonidal infections, current management. Christensen MA. April 184.

Pitcher's elbow in adolescents. Grana WA. June 33.

Plants and dermatitis. See Poison ivy rash.

Pneumonia, antibiotics, rational selection for. Griffin FM Jr. Jan 47.
cause, zeroing in on. Joseph P. Feb 47.
and influenza, vaccination recommendations. Palmer DL. Oct 29.

newer causes. Heineman HS. Dec 49.
refractory, treating patients. Yoshikawa TT. March 95.

tularemia. See Clinical Cases No. 82, June 176.

Pneumonitis. See Clinical Cases No. 77, Jan 188.

Poison ivy rash maybe, maybe not. Schorr WF. July 37.

Polymyalgia rheumatica, when a patient 'hurts all over.' Healey LA. March 153.

Polyps, colon, management the key to cancer prevention. Panish JF, Sherlock P. Oct 119.
rectal, what you can do. Kraft SC. April 219.

Postnasal drip, when is it a problem? Marlowe FI. April 83.

Practical Pointers (see also Tips).

Anxiety and depression, approach to what's bothering the patient. July 44.

Cactus thorns, removing. Oct 182.

Carpal tunnel syndrome. Sept 58.

Cloth compress, diapers. April 268.

Collar a snorer. Jan 147.

Compliance, using a watch with alarm as reminder. June 130.

Debriding skin blister from a burn, shave first. June 130.

Dentures, look under—for cancer, tumors. March 37.

Drawing blood and blood pressure reading—not in that arm. Feb 66.

Eye, chemical burns. Dec 96.

Eye, ophthalmic ointment. Feb 181.

Eye, retina exam in children. July 44.

Fatigue, is it psychogenic? Jan 147.

Fussy baby? Jan 147.

Gluconator for spasm. Aug 125.

Hematomas from punctures, unnecessary. Jan 266.

Ice pack, homemade. Feb 66.

Insulin, Rx for premed. Sept 58.

Insulins, refrigeration not necessary. Sept 139.

Interdigital tinea pedis. April 33.

Laryngotomy, voice recordings prior to. Oct 182.

YEAR-END INDEX

- Lipoatrophy, treating. Dec 96.
 'Little man' for little children. Jan 266.
 Metabolic acidosis, high-anion-gap. June 130.
 Nails can be sawed. April 33.
 Nasal packing removal. Dec 96.
 Neck rigidity, determining in children. Feb 66.
 Nylon sutures and static electricity. Nov 266.
 Otitis media, 'do it yourself' test. Feb 181.
 Parenteral, varying injection sites. Sept 139.
 Records on hand. Nov 266.
 Senile confusion or hypothyroidism? July 44.
 Skin tags, unsightly. April 268.
 Speculum, warming. Aug 125.
 Stethoscope earpieces. Aug 125.
 Stirrups and gowns for examination. Oct 182.
 'Stroke' or hypoglycemia? Feb 181.
 Subungual hematoma—drill for blood. March 37.
 Suture reinforcement. Aug 125.
 Swan-Ganz pressure measurements, reading. April 33.
 Tape it open. Jan 266.
 Telephone communications, better. Nov 266.
 Ticks, removing by freezing and tweezing. April 268.
 Time clock for up-to-the-minute practice management. Jan 147.
 Tourniquet for elderly patients. Sept 139.
 Urethritis—don't ignore the partner. March 37.
 Urine test strips for visually impaired diabetics. Nov 266.
Pregnancy, caesarean deliveries, why so many—are they justified? Petrie RH, Gimovsky ML. Jan 88.
 and diabetes. Ifly L. Aug 61.
 drugs during pregnancy, prescribing practices: some suggestions. Goplerud CP. April 29.
 and hypertension, guiding patient toward safe delivery. Stenchever MA. Nov 82.
Premenstrual tension, not 'all in her head.' Chihal HJ. Oct 99.
Preventive care. See Screening.
Proctology. See Polyps.
Prostatitis, a spectrum of diseases. Gardner WG. May 91.
Protein loss, protein-losing enteropathies: 'hidden disease.' Schwabe AD. March 111.
Pseudomonadaceae, microbiology update. Bryan CS. April 163.
Psoriasis, psoriatic arthritis, diagnostic dilemmas and therapeutic options. Namey TC. Oct 236.
Pulmonary diseases. See Respiratory disease.
Puzzling Cases:
 Case of mismanagement (purpura due to quinidine). Grossman J. Dec 145.
 Has the ulcer recurred (gastric carcinoma)? Barkin JS. Feb 235.
 Homosexual man with chronic diarrhea (giardiasis). Rogers A. Nov 55.
 Laborer with the sore arm (C7 radiculopathy). Smith B. July 79.
 Man with recurrent chest pain (diffuse esophageal spasm). Perloff JK. April 93.
 Unexplained abdominal pain (Zollinger-Ellison syndrome). Rogers A. Feb 148.
 Why the gross rectal bleeding (colonic vascular dysplasia)? Barkin J. June 153.
 Why the postoperative diarrhea (cholaretic diarrhea)? Barkin J. Oct 218.
 Woman with anemia. Grossman J. Sept 240.
Questionnaire. See APGAR questionnaire.
Questions physicians often ask . . .
 asthma (10). Falliers CJ. Nov 233.
 chronic pain (10). Murphy TM. March 27.
 coronary artery disease, diagnostic studies (10). Berger BC, Brest AN. Aug 215.
 diarrhea (10). Farmer RG. May 23.
 gastric ulcer (10). Flesher B. Dec 68.
 screening athletes (10). Hirata I. Oct 39.
Quinidine. See Drugs.
Radiculopathy, C7. See Puzzling Cases,
 Laborer with the sore arm.
Rectal bleeding. See Bleeding.
Rectal polyps. See Polyps.
Reflux esophagitis. See Clinical Cases
 No. 83, July 212.
Refugees, health care for. Smilkstein G. Sept 185.
Respiratory diseases, adult respiratory distress syndrome, rare but dangerous. Khan MA. July 69.
 asbestos and lung disease. Greenberg SD. Aug 37.
 aspergillosis. **See Clinical Cases** No. 88, Dec 158.
 chronic obstructive pulmonary disease. **See Clinical Cases** No. 81, May 174.
 'nonsurgical' biopsy techniques for lung disease. Rhodes ML. June 61.
 spirometry in office, part of routine physical exam. Cherniack R. Oct 187.
 See also **Clinical Cases** No. 77, Jan 188, and specific subjects.
Retirement, physician. Fisher JV. Aug 227.
Rheumatic disease. See Arthritis.
Rubeola. See Measles.
Screening, alcoholism (Michigan Alcoholism Screening Test). May 86.
 athletes, physicians' questions (10). Hirata I. Oct 39.
 evaluation of trauma. McFee AS. Dec 37.
 gallstones, silent: high-risk persons. Tangedahl TN, Dyck WP. Feb 113.
 routine checkup—what to screen for. Siegel F. Jan 27.
 TB, hospital employees, ins and outs (Brief Consultation). Bobrowitz ID. Feb 211.
Seizures, employment guidelines for epileptics (Brief Consultation). Engel J Jr, Goldensohn E. Oct 177.
 first in an adult (Brief Consultation). Livingston S. July 231.
 first seizure management in adults, essentials of. Raskind R. Jan 217.
Sex, contraception for adolescent girls. DeLia JE. March 63.
 counseling arthritic patients. Renshaw DC. Dec 89.
 and genital herpesvirus, managing. Curole DN. June 47.
 sexual abuse of adolescents, how to recognize and deal with a delicate problem. Downes M, Orr DP. Nov 37.
 sexual practices, modern view of ancient taboos. Renshaw DC. Sept 207.
Sexual dysfunction, delayed menarche, causes and management. Bongiovanni AM. July 53.
Shingles. See Herpes zoster.
Shock, cardiogenic, earlier recognition and treatment. Wright EM, Beller GA. Sept 72.
 hemorrhagic, some therapy controversies. Pestana C. Aug 87.
Skating accidents, a new epidemic. Keller EL. April 37.
Skin, and athletic activity. Levine N. Aug 114.
 cosmetic peeling, how deep before referral? Barkoff JR. Nov 127.
 cosmetics, hazards of. Fisher AA. Feb 172.
 disorders, clues to unrecognized or uncontrolled diabetes. Roenigk HH Jr. Oct 136.
 eruptions caused by drugs. Odom RB, Berger TG. May 55.
 purpura caused by quinidine. **See Puzzling Cases, Case of mismanagement.**
 See also **Dermatitis, Skin lesions, and Urticaria.**
Skin lesions, common premalignant and malignant. Bart BJ. March 146.
Sleep disorders, centers, for which patients? Mitler MM, Dement WC. Jan 155.
 narcolepsy and sleep apnea, recognition and management. Orr WC. Feb 202.
Sperm. See Azoospermia.
Spirometry, in office, part of routine physical exam. Cherniack R. Oct 187.
Sports, basketball injuries and the like, practical advice. Apple DF Jr. Jan 71.
 dermatologic consequences of athletic activity. Levin N. Aug 114.
 knee, 'Doctor, my knee keeps going out on me.' Leach RE. May 152.
 knee injury, how severe? Reckling FW. Jan 233.
 pitcher's elbow in adolescents. Grana WA. June 33.
 screening athletes, physicians' questions (10). Hirata I. Oct 39.
 skating accidents: a new epidemic. Keller EL. April 37.
 sports-related problems of women. Haycock CE. July 234.
Sputum specimens, zeroing in on cause of pneumonia. Joseph P. Feb 47.
Stroke, evaluation and management of cerebrovascular disease. Ellison JP. June 89.
Sudden infant death syndrome, still a mystery. Reece RM. Feb 125.
Surgery, for chronic pancreatitis—when and what kind? Cooperman AV. Feb 163.
 for diabetic patients, preoperative care. Whitehouse FW. Dec 151.

YEAR-END INDEX

- for diverticular disease. Jagelman DG. Oct 195.
- obese patient. Wachtel TJ. Aug 123.
- Syphilis.** See **Venereal disease.**
- Systemic lupus erythematosus.** improved prognosis for today's patient. Glynn MJ, Davis JS. Nov 103.
- Temporal arteritis.** See **Giant cell arteritis.**
- Tests,** cancer, laboratory tests for. Nichols WS, Nakamura RM. June 131.
- diagnostic, why and when to use microbiology lab. Heineman HS. May 101.
- noninvasive G.I. Segal HL. Dec 101.
- See also **Screening.**
- Theophylline.** See **Drugs.**
- Thrombosis,** deep vein, modern approach to. Lerner RG. July 191.
- Thyroiditis,** differentiating and treating types. Cherner R. May 31.
- Hashimoto's (Brief Consultation). Hamburger JI. Aug 173.
- Tips** (see also **Practical Pointers**).
- Ampicillin rash indicates mono. Aug 194.
- Blood gas determinations, imaginary triangle marks needle puncture spot. July 175.
- Blood gas determinations, misery free. Feb 144.
- Fingernail suture. Aug 138.
- Hand vein isolation. Jan 186.
- Hemiblocks, diagnosing. March 178.
- Ingrown toenails, treating thick, rough. March 157.
- Knee effusions, aspirating. Nov 227.
- Lidocaine allergy? June 128.
- Median nerve palsy? Dec 132.
- Multiple medications, an ounce of prevention. Feb 234.
- Neurologic examination—fingers tell the story. May 90.
- Operate or 'obstinate'? Feb 103.
- Parkinson's disease, monitoring. Jan 172.
- Pleural tap, safer, easier, for diagnosis. Jan 144.
- Scissors and hammer in lab coat. Jan 228.
- Spinal x-rays, logroll for. May 26.
- Tennis elbow? Aug 101.
- Thoracentesis variation. Feb 277.
- Tracheal aspiration. Oct 198.
- Wounds, removing grit. April 277.
- Toxoplasmosis,** prevention and treatment. Feldman HA. Feb 215.
- Tranquilizers.** See **Drugs.**
- Travel advice,** vaccination. Jan 209; Aug 177.
- Trichinosis,** forgotten but not gone. Most H. Sept 101.
- Tuberculosis screening,** hospital employees, ins and outs (Brief Consultation). Bobrowitz ID. Feb 211.
- Tularemia.** See **Clinical Cases** No. 82, June 176.
- Tumors,** acoustic nerve, what to do about. Gacek RR. July 110.
- bladder, current management of benign and malignant. Oldani GO, Grabstald H. Feb 238.
- ovarian and other pelvic. Katz AR. Dec 27.
- Ulcer.** See **Clinical Cases** No. 79, March 133; **Puzzling Cases**, Has the ulcer recurred? See also Dec 68.
- Urinalysis,** simple diagnostic procedure rich with clues. Swerdlow MA, Jao W. Oct 265.
- Urinary tract infections,** newest thinking. Krieger JN, Mandell GL. April 224.
- Urologic disorders.** Urinary incontinence. See **Clinical Cases** No. 87. See also **Prostatitis and Urinary tract infections.**
- Urticaria,** cause. Prawer SE, Katz HI, Hien NT. Feb 265.
- Vaccination,** for childhood diseases, changing views. Marcuse EK. Nov 271.
- travel advice. Jan 209; Aug 177.
- See also **Influenza.**
- Vaginal infection,** diagnosing and treating. Fiuma: a NJ. Feb 281.
- Vascular dysplasia,** colonic. See **Puzzling Cases**, Why the gross rectal bleeding?
- Vascular ectasia,** in rectal bleeding. Abel WG, Willner JS. Feb 223.
- Venereal disease,** gonococcal sepsis, mimics other disorders. Williams RC Jr. Sept 222.
- stigmata of syphilis. Jan 244.
- See also **Vaginal infection.**
- Ventricular hypertrophy,** using ECG to zero in on. Canedo MI. July 155.
- Ventricular premature contractions,** how to manage. Cohen LS. July 96.
- Viral hepatitis.** See **Hepatitis.**
- Volunteer service,** short-term medical assistance overseas. Smilkstein G. Sept 191.
- Warfarin.** See **Drugs.**
- Weight reduction.** See **Obesity and Clinical Cases** No. 86, Oct 222.
- Women and sports.** See **Sports.**
- Wrist injury,** primary care. Clark JM, Matsen FA. Sept 38.
- X-rays.** See **Irradiation.**
- Zollinger-Ellison syndrome.** See **Clinical Cases** No. 79, March 133; **Puzzling Cases**, Unexplained abdominal pain.
- Zoonoses,** common. Goscienski PJ. April 231.
- dermatologic manifestations. Burnett JW. Dec 137.

INDEX TO AUTHORS

- Abel, William G., vascular ectasia in rectal bleeding. Feb 223.
- Achord, James L., non-A, non-B hepatitis. Jan 204.
- Alexander, Sidney, new cardiovascular drugs. June 73; newer antihypertensive drugs. July 135; new antiarrhythmic agents. Aug 107.
- Almy, Thomas P., diverticular disease. Sept 160.
- Apple, David F., Jr., basketball injuries. Jan 71.
- Bailey, R. Elizabeth, warfarin interactions with other drugs. April 281.
- Baran, Daniel T., osteoporosis. April 57.
- Barkin, Jamie S., gastric carcinoma (Puzzling Case). Feb 235; colonic vascular dysplasia (Puzzling Case). June 153; postoperative diarrhea (Puzzling Case). Oct 218.
- Barkoff, Joel R., cosmetic peeling. Nov 127.
- Bart, Bruce J., premalignant and malignant skin lesions. March 146.
- Beller, George A., cardiogenic shock. Sept 72.
- Benditt, David G., digitalis therapy. stopping. Feb 137.
- Berger, Bruce C., diagnostic studies in coronary artery disease (physicians' questions). Aug 215.
- Berger, Timothy G., cutaneous drug reactions. May 55.
- Berk, Paul D., hepatic failure. March 182.
- Biddle, Thomas L., myocardial infarction. March 38.
- Black, Martin, jaundice. July 120.
- Blackwell, Barry, noncompliance. Jan 259.
- Bobrowitz, Isidore D., TB screening of hospital employees (Brief Consultation). Feb 211.
- Bonamo, John J., ankle ligament injuries. Oct 147.
- Bongiovanni, Alfred M., delayed menarche. July 53.
- Brest, Albert N., diagnostic studies in

YEAR-END INDEX

- coronary artery disease (physicians' questions), Aug 215.
- Bryan, Charles S.**, 'new faces of old enemies' (series of 8), meningococcus, Jan 101; *Hemophilus influenzae*, Feb 229; Enterobacteriaceae, March 193; Pseudomonadaceae, April 163; *Bacteroides fragilis*, May 207. In 1980: pneumococcus, Oct 159; streptococcus, Nov 33; staphylococcus, Dec 83.
- Burnett, Joseph W.**, zoonoses, Dec 137.
- Bynum, T.E.**, chronic abdominal pain (Brief Consultation), Nov 163.
- Calesnick, Benjamin**, alcohol and medications, Aug 193.
- Calverley, John R.**, electromyography, Sept 213.
- Canedo, Mario I.**, ventricular hypertrophy, July 155.
- Carliner, Nathan H.**, quinidine, Nov 256.
- Carter, Stephen K.**, breast cancer, Sept 51.
- Casey, Joan**, infections in diabetic patients, May 169.
- Chahine, Robert A.**, mitral regurgitation, Sept 129.
- Cherner, Rachmel**, thyroiditis, May 31.
- Cherniack, Reuben**, office spirometry, Oct 187.
- Chihal, H. Jane**, premenstrual tension, Oct 99.
- Christensen, Mark A.**, pilonidal infections, April 184.
- Clark, John M.**, injured wrist, Sept 38.
- Cohen, Lawrence S.**, ventricular premature contractions, July 96; infective endocarditis (Clinical Case No. 86), Oct 222; pacemaker implantation (Brief Consultation), Oct 285.
- Cohen, Marc S.**, azoospermia (Brief Consultation), Feb 249.
- Cohen, Stafford I.**, refractory tachyarrhythmias, Oct 107.
- Coodley, Eugene L.**, myocardiopathy, May 44.
- Cooperman, Avram M.**, chronic pancreatitis, surgery, Feb 163.
- Cruse, Joseph**, alcoholism and hard-drug dependency among physicians, Nov 297.
- Curole, David N.**, genital herpesvirus, June 47.
- Danehower, Richard L.**, infective endocarditis (Clinical Case No. 86), Oct 222.
- Daniel, William A., Jr.**, adolescents, Sept 107.
- Davidson, John K.**, diet for overweight diabetic patients, Jan 251.
- Davis, John S.**, SLE, Nov 103.
- Deaton, John**, Down's syndrome, April 249.
- DeLia, Julian E.**, contraception for adolescents, March 63.
- Dement, William C.**, sleep disorders, Jan 155.
- Diamond, Seymour**, migraine, Jan 131.
- Diefenbach, William C.L.**, tularemia (Clinical Case No. 82), June 176.
- DiGiacomo, Joseph N.**, major tranquilizers, Nov 68.
- Doherty, James E.**, antiarrhythmic agents, Dec 80.
- Downes, Maureen**, adolescent sexual abuse, Nov 37.
- Dwyer, John M.**, HL-A markers, June 111.
- Dyck, Walter P.**, screening for silent gallstones, Feb 113.
- Ellenberg, Max**, diabetic neuropathy in the elderly, April 113.
- Ellison, Jeffrey P.**, cerebrovascular disease, June 89.
- Engel, Jerome**, employment guidelines for epileptics (Brief Consultation), Oct 177.
- Falliers, Constantine J.**, asthma (physicians' questions), Nov 233.
- Fantl, J. Andrew**, urinary incontinence (Clinical Case No. 87), Nov 204.
- Farmer, Richard G.**, diarrhea (physicians' questions), May 23.
- Feldman, Harry A.**, toxoplasmosis, Feb 215.
- Finnerty, Frank A., Jr.**, hypertension compliance, March 80.
- Fisher, Alexander A.**, hazards of cosmetics, Feb 172.
- Fisher, Joseph V.**, physician retirement, Aug 227.
- Fisher, Michael L.**, quinidine, Nov 256.
- Fiumara, Nicholas J.**, vaginal infection, Feb 281.
- Fleshler, Bertram**, gastric ulcer (physicians' questions), Dec 68.
- Frank, Samuel B.**, perioral dermatitis, Jan 143.
- Frenkel, Lawrence D.**, rubeola, Feb 94.
- Friedewald, Vincent E., Jr.**, hypertrophic subaortic stenosis (Clinical Case No. 78), Feb 254.
- Friedman, Arnold P.**, organic and systemic causes of headache, March 205; chronic tension headaches, June 147.
- Gacek, Richard R.**, acoustic nerve tumors, July 110.
- Gardner, William G.**, prostatitis, May 91.
- Gifford, Roy W., Jr.**, resistant hypertension, June 220.
- Gimovsky, Martin L.**, caesarean deliveries, Jan 88.
- Ginsburg, David**, renal hypertension, Aug 140.
- Glickman, Franklin S.**, hidradenitis suppurativa (Clinical Case No. 85), Sept 228.
- Glober, Gary**, Zollinger-Ellison syndrome (Clinical Case No. 79), March 133.
- Glynn, Martin J.**, SLE, Nov 103.
- Goldensohn, Eli**, employment guidelines for epileptics (Brief Consultation), Oct 177.
- Goplerud, Clifford P.**, drugs during pregnancy, April 29.
- Gordan, Gilbert S.**, postmenopausal estrogen replacement (Brief Consultation), May 50; endocrine therapy for disseminated breast cancer, Nov 141.
- Goscienski, Philip J.**, common zoonoses, April 231.
- Gotto, Antonio M.**, exercise and heart disease, Oct 52.
- Grabstald, Harry**, bladder tumors, Feb 238.
- Grana, William A.**, pitcher's elbow in adolescents, June 33.
- Gray, James E.**, reflux esophagitis (Clinical Case No. 83), July 212.
- Greenberg, S. Donald**, asbestos and lung disease, Aug 37.
- Gregoratos, Gabriel**, aortic valve disease,

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2. The extrapyramidal symptoms which can occur secondary to Tigan may be confused with the central nervous system signs of an undiagnosed primary disease responsible for the vomiting, e.g., Reye's syndrome or other encephalopathy.
3. It has been suspected that drugs with hepatotoxic potential, such as Tigan, may unfavorably alter the course of Reye's syndrome. Such drugs should therefore be avoided in children whose signs and symptoms (vomiting) could represent Reye's syndrome. It should also be noted that salicylates and acetaminophen are hepatotoxic at large doses. Although it is not known that at usual doses they would represent a hazard in patients with the underlying hepatic disorder of Reye's syndrome, these drugs, too, should be avoided in children whose signs and symptoms could represent Reye's syndrome, unless alternative methods of controlling fever are not successful.

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YEAR-END INDEX

- Jan 60; Feb 87.
- Griffin, Frank M., Jr.**, antibiotics for pneumonia, Jan 47.
- Groshong, Ted**, lactic acidosis, May 114.
- Grossman, Joshua**, anemia (Puzzling Case), Sept 240; purpura due to quinidine (Puzzling Case), Dec 145.
- Gucker, Thomas, 3rd**, limping in youngsters, June 194.
- Hamburger, Joel I.**, Hashimoto's thyroiditis (Brief Consultation), Aug 173.
- Hammermeister, Karl E.**, coronary bypass, Jan 154.
- Harper, John F.**, infective endocarditis, April 43.
- Hartung, G. Harley**, exercise and heart disease, Oct 52.
- Haycock, Christine E.**, sports-related problems of women, July 234.
- Healey, Louis A.**, polymyalgia rheumatica, March 153; occult giant cell arteritis, July 227; rheumatic syndromes, Aug 97.
- Heineman, Herbert S.**, microbiology lab, May 101; pneumonia, Dec 49.
- Hien, Ngo Thanh**, urticaria, Feb 265.
- Hirata, Isao**, screening athletes (physicians' questions), Oct 39.
- Howell, Douglas A.**, diverticular disease, Sept 160.
- Howland, W. Slocum, Jr.**, upper extremity dislocations, Feb 183.
- Huff, Thomas A.**, exercise planning for insulin-dependent diabetics, Feb 71.
- Iffy, Leslie**, diabetes and pregnancy, Aug 61.
- Izsak, E. Moshe**, viral hepatitis, Feb 155.
- Jagelman, David G.**, diverticular disease, Oct 195.
- Jao, Wellington**, urinalysis, rich with clues, Oct 265.
- Joseph, Patrick**, pneumonia cause, Feb 47.
- Katz, Allan R.**, pelvic mass, Dec 27.
- Katz, Arnold E.**, hearing problems, Jan 38.
- Katz, Harry I.**, urticaria, Feb 265.
- Keller, Eugene L.**, skating accidents, April 37.
- Khan, M. Anees**, adult respiratory distress syndrome, July 69.
- Kinlaw, W. Bernard**, postinfarction symptoms (Brief Consultation), Feb 293; postinfarction arrhythmias (Brief Consultation), May 205.
- Kleinman, Martin S.**, diagnostic advances in liver, gallbladder, and pancreatic disease, April 71.
- Knochel, James P.**, hypokalemia (Brief Consultation), Sept 201.
- Kolder, Hansjoerg**, cataract therapy, April 147.
- Kouchoukos, Nicholas T.**, coronary bypass, Jan 121.
- Kraft, Sumner C.**, rectal polyps, April 219.
- Krieger, John N.**, urinary tract infections, April 224.
- Krumlovsky, Frank A.**, renal hypertension, Aug 140.
- Lamphier, Timothy A.**, small-bowel obstruction, Jan 165.
- Lanzkowsky, Philip**, iron deficiency in adolescents, Aug 164.
- Lea, A. Scott**, choosing 'proper' cephalosporin, April 101; choosing 'proper' aminoglycoside, July 27.
- Leach, Robert E.**, knee instability, May 152.
- Leaman, David M.**, cardiac catheterization for murmurs, May 138.
- Legerton, C.W.**, irritable bowel syndrome, June 25.
- Leif, Harold L.**, circumcision of the clitoris (Brief Consultation), March 167.
- Leis, Henry Patrick, Jr.**, breast cancer, Aug 128.
- Lerner, Robert G.**, deep vein thrombosis, July 191.
- Levine, Norman**, skin and sports, Aug 114.
- Lifschitz, Meyer D.**, nephrotic syndrome—nil lesion (Clinical Case No. 84), Aug 180.
- Livingston, Samuel**, first seizure in an adult (Brief Consultation), July 231.
- Livstone, Elliot M.**, nutritional needs of cancer patient, April 175.
- Loggie, Jennifer M.H.**, pediatric hypertension, Oct 245.
- Lueg, Mark C.**, hyperglycemic dehydration, Nov 91.
- Mabry, Richard L.**, stuffy nose, Sept 29.
- Maisel, Robert H.**, broken nose, May 74.
- Malone, John L.**, ketoacidosis in the young, July 176.
- Maloy, William C.**, pacemaker implantation (Brief Consultation), Oct 285.
- Mandell, Gerald L.**, immune system defects, March 55; urinary tract infections, April 224.
- Marcuse, Edgar K.**, immunization for childhood diseases, Nov 271.
- Marks, Alan R.**, radiation exposure and lymphoid malignancy (Brief Consultation), Nov 89.
- Marlowe, Frank L.**, postnasal drip, April 83.
- Matsen, Frederick A.**, injured wrist, Sept 38.
- McCarthy, John J., Jr.**, natural family planning, Dec 109.
- McCoy, James R.**, hand injuries, April 126.
- McFee, Arthur S.**, multiple injuries, Dec 37.
- Medina, Jose L.**, migraine, Jan 131.
- Melnick, Arnold**, adolescent fatigue, July 150.
- Mittler, Merrill M.**, sleep disorders, Jan 155.
- Most, Harry**, trichinosis, Sept 101.
- Murata, Stephen K.**, editorials: Cost containment and indivisibility of life, Feb 294; Patient Package Inserts, March 224; Clinical pearls and you, April 288; Clinical significance of patent life, Sept 256.
- Murphy, Terence M.**, chronic pain (physicians' questions), March 27.
- Nagel, Philip**, chronic hepatitis, Nov 48.
- Nakamura, Robert M.**, laboratory tests for cancer, June 131.
- Namey, Thomas C.**, psoriatic arthritis, Oct 236.
- Nattel, Stanley**, drugs for the elderly, Sept 87.
- Nichols, W.S.**, laboratory tests for cancer, June 131.
- Norman, Dean C.**, bacterial meningitis, Nov 219; nonbacterial meningitis, Dec 175.
- Oberman, Albert**, post-bypass exercise,

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YEAR-END INDEX

- Nov 177.
- Odum, Richard B.**, cutaneous drug reactions, May 55.
- Oldani, Gregory**, bladder tumors, Feb 238.
- Orr, Donald P.**, adolescent sexual abuse, Nov 37.
- Orr, William C.**, narcolepsy and sleep apnea, Feb 202.
- Pagliara, Anthony S.**, ketoacidosis, March 121.
- Palmer, Darwin L.**, infections in the elderly, Aug 201; influenza and pneumonia, Oct 29.
- Panish, Joel F.**, colon polyps, Oct 119.
- Patel, Dinesh**, arthroscopy of the knee, Sept 118.
- Perloff, Joseph K.**, diffuse esophageal spasm (Puzzling Case), April 93.
- Pestana, Carlos**, hemorrhagic shock, Aug 87.
- Petrie, Roy H.**, caesarean deliveries, Jan 88.
- Pope, Richard M.**, anti-inflammatory drugs, choosing, Feb 29.
- Prawer, Steven E.**, urticaria, Feb 265.
- Pruitt, Basil A., Jr.**, early burn care, Nov 192.
- Rackley, Charles E.**, coronary bypass, Jan 121.
- Raffin, Thomas A.**, chronic obstructive pulmonary disease (Clinical Case No. 81), May 174.
- Raj, P. Prithvi**, herpes zoster, March 71.
- Rakita, Louis**, orthostatic hypotension (Brief Consultation), June 217.
- Ram, C. Venkata S.**, hypertensive encephalopathy, Jan 177; primary aldosteronism, Dec 211.
- Raskin, David E.**, agoraphobia, anxiety, panic (Clinical Case No. 80), April 262.
- Raskind, Robert**, first seizure in an adult, Jan 217.
- Reckling, Frederick W.**, knee injury, Jan 233.
- Reece, Robert M.**, sudden infant death syndrome, Feb 125.
- Reidenberg, Marcus M.**, protein binding of drugs, July 59.
- Renshaw, Domeena C.**, circumcision of clitoris (Brief Consultation), March 167; sexual practices, ancient taboos, Sept 207; arthritis and sex, Dec 89.
- Rhodes, Mitchell L.**, 'nonsurgical' biopsy techniques for lung disease, June 61.
- Riely, Caroline A.**, nutritional therapy and the liver, May 194.
- Rivlin, Richard S.**, obesity, June 125.
- Roelnigk, Henry H., Jr.**, skin disorders in diabetes, Oct 136.
- Rogers, Arvey**, Zollinger-Ellison syndrome (Puzzling Case), Feb 148; giardiasis (Puzzling Case), Nov 55.
- Roth, Thomas**, insomnia, Oct 203.
- Russell, Richard O., Jr.**, coronary bypass, Jan 121.
- Sack, Kenneth E.**, physical therapy for rheumatoid arthritis, July 171.
- Sandzen, Sigurd C.**, burns of hands and arms, part 1, Sept 142; part 2, Oct 77.
- Sarokhan, Carol T.**, low-back pain, radiologic guide, part 1, Nov 27; part 2, Dec 192.
- Schorr, William F.**, poison ivy rash?, July 37.
- Schottenfeld, Mark**, hip pain, Aug 47.
- Schwabe, Arthur D.**, protein loss, March 111.
- Schwartz, Gordon F.**, mastectomy follow-up (Brief Consultation), March 143; breast cancer, Oct 162.
- Schwartz, Leroy**, generic substitution (editorial), Oct 290.
- Schwartz, Steven O.**, aplastic anemia from benzene compound (Brief Consultation), Aug 158.
- Segal, Harry L.**, noninvasive tests for G.I. cancer, Dec 101.
- Sharma, Om P.**, pigeon breeder's disease (Clinical Case No. 77), Jan 188; aspergillosis (Clinical Case No. 88), Dec 158.
- Sheffer, Albert L.**, angioedema, Sept 173.
- Sherlock, Paul**, colon polyps, Oct 119.
- Shuman, Charles R.**, problems in elderly diabetic patients, June 54.
- Siegel, Frances**, routine checkup, screening, Jan 27.
- Skillem, Penn G.**, improving patient cooperation, July 206.
- Smilkstein, Gabriel**, Family APGAR questionnaire, March 170; health care for refugees, Sept 185; volunteer service overseas, Sept 191.
- Smith, Bernard**, C7 radiculopathy (Puzzling Case), July 79.
- Smith, Linda Jane**, electromyography, Sept 213.
- Spiro, Howard**, chronic abdominal pain (Brief Consultation), Nov 163.
- Steelman, R. Barrett**, infective endocarditis, April 43.
- Stenchever, Morton A.**, hypertension and pregnancy, Nov 82.
- Stewart, Bruce H.**, azoospermia (Brief Consultation), Feb 249.
- Swerdlow, Martin A.**, urinalysis, rich with clues, Oct 265.
- Tangedahl, Tim N.**, screening for silent gallstones, Feb 113.
- Taylor, Addison A.**, mild hypertension, May 225.
- Thomas, Kenneth E.**, pacemaker implantation (Brief Consultation), Oct 285.
- Tzagournis, Manuel**, hypertension and diabetes, Sept 247.
- Urban, Jerome A.**, mastectomy follow-up (Brief Consultation), March 143.
- Vander Ploeg, Darl E.**, allergic dermatitis, Sept 65.
- Vaughan, Cynthia**, endocrine therapy for disseminated breast cancer, Nov 141.
- Verani, Mario S.**, mitral regurgitation, Sept 129.
- Vidt, Donald G.**, diuretics for hypertension, April 242.
- Wachtel, Tom J.**, obesity and surgery, Aug 123.
- Walz, Thomas H.**, geriatric compliance, Oct 65.
- Weber, Edward R.**, hand injuries, April 126.
- Weiss, Gerson**, contraception, Nov 285.
- Weissman, Barbara N.W.**, low-back pain, radiologic guide, part 1, Nov 27; part 2, Dec 192.
- Whitehouse, Fred W.**, insulin therapy complications, April 275; diabetes and surgery, Dec 151.
- Whitfield, Charles L.**, alcoholism, May 81; June 101.
- Whittier, Frederick C.**, hypernatremia, June 206.
- Williams, Glenys O.**, geriatric compliance, Oct 65.
- Williams, Ralph C., Jr.**, gonococcal sepsis, Sept 222.
- Williams, Temple W., Jr.**, choosing 'proper' cephalosporin, April 101; choosing 'proper' aminoglycoside, July 27.
- Willner, Jeffrey S.**, vascular ectasia in rectal bleeding, Feb 223.
- Winter, Stephen L.**, chronic hepatitis, Nov 48.
- Witham, A. Calhoun**, unusual ECGs of patients with no heart disease, April 193.
- Wolf, Stewart**, nausea, Aug 27.
- Wolinsky, Harvey**, diabetes mellitus and cardiovascular complications, July 84.
- Wright, Edward M.**, cardiogenic shock, Sept 72.
- Wyatt, Richard A.**, theophylline in asthma management, May 124.
- Yoshikawa, Thomas T.**, refractory pneumonia, March 95; bacterial meningitis, Nov 219; nonbacterial meningitis, Dec 175.
- Zelis, Robert F.**, cardiac catheterization for murmurs, May 138.
- Zorick, Frank**, insomnia, Oct 203.